

SCHEDULING STATUS: S2

**PROPRIETARY NAME
(AND DOSAGE FORM):**

BETADINE® DOUCHE (SOLUTION)

COMPOSITION:

Each 1 ml contains povidone-iodine 100 mg, equivalent to 10 mg available iodine.

PHARMACOLOGICAL CLASSIFICATION:

A. 18.6 Vaginal Preparations

PHARMACOLOGICAL ACTION:

Povidone-iodine is a multivalent broad spectrum local antiseptic having bactericidal and fungicidal properties. The effect on vegetative cells of various bacteria and fungi is due to the liberation of free iodine from the complex. Many viruses, protozoa, yeasts, cysts and spores are also susceptible.

INDICATIONS:

1. Trichomonal, monilial, bacterial and non-specific vaginitis.
2. Cleansing and deodorising douche.

CONTRA-INDICATIONS:

Sensitivity to povidone-iodine. Patients with non-toxic nodular colloid goitre should not use povidone-iodine. This product is spermicidal and should not be used when conception is desired.

WARNINGS AND SPECIAL PRECAUTIONS:

1. Not to be used by persons who are allergic to iodine.
2. Not to be used in pregnancy or by lactating women.
3. Alkalis will reduce the activity of this preparation.
4. Absorption of povidone-iodine may interfere with thyroid function tests.
5. This product is spermicidal and should not be used when conception is desired.

DOSAGE AND DIRECTIONS FOR USE:

Use as **Therapeutic Douche** -

Add two medicine measures (10 ml) of **BETADINE® DOUCHE** to the squeeze bottle. Fill the squeeze bottle with lukewarm water. Screw the applicator to the squeeze bottle and shake gently. Carefully insert the applicator high into the vagina without causing discomfort. Expel as much cleansing liquid as possible by applying gentle pressure on the sides of the squeeze bottle, allowing the solution to run freely from the vagina. Remove the applicator from the vagina allowing air to enter the squeeze bottle, so that it regains its original shape.

Reinsert the applicator into the vagina squeezing once again to cleanse the vagina thoroughly. Repeat until all the **BETADINE® DOUCHE** has been used. Finally rinse away the excess solution from around the vagina. Pat dry the vaginal area with a clean cloth or paper towel. Rinse clean the empty bottle and applicator in warm water and store for further use. Use once per day for 7 – 14 days or as directed by the physician.

Use as **Cleansing and Deodorising Douche** -

Add one medicine measure (5 ml) of **BETADINE® DOUCHE** to the squeeze bottle. Fill the squeeze bottle with lukewarm water. Use as per the instructions under **Therapeutic Douche**. Use once or twice weekly, or as directed by the physician.

SIDE-EFFECTS:

Povidone-iodine sensitivity may develop in certain individuals. If irritation, discomfort, redness, swelling or other signs of sensitivity occur, the patient should discontinue use and consult her physician.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Systemic effects include metabolic acidosis, hypernatraemia and renal impairment. Treatment is symptomatic and supportive.

IDENTIFICATION:

BETADINE® DOUCHE is a dark brown aqueous liquid with a floral odour.

PRESENTATION:

BETADINE® DOUCHE is available in a white or beige, polyethylene container containing 250 ml of liquid with a transparent polyethylene spout and a blue polypropylene cap. The **BETADINE® DOUCHE Kit** also contains a blue empty squeeze bottle and vaginal applicator.

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:**South Africa:**

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